

CLAIMS:

1. A process for preparing A1AT from A1AT-containing solutions, comprising the following steps:
  - (a) subjecting an A1AT-containing solution to ion-exchange chromatography;
  - (b) adding detergents and optionally a solvent for inactivating lipid-enveloped viruses;
  - (c) followed by increasing the salt concentration to salt out the detergents.
2. The process according to claim 1, wherein said A1AT-containing solution has been obtained from blood plasma or its fractions, preferably from a reconstituted plasma fraction IV1 (Cohn), or is derived from a recombinantly or transgenically expressed A1AT preparation or a fermentation supernatant.
3. The process according to claim 1 and/or 2, wherein ion-exchange chromatography is performed on an anion-exchange gel, preferably DEAE-Sepharose® or DEAE-Sepharose® Fast Flow.
4. The process according to any of claims 1 to 3, wherein said virus inactivation according to step (b) is effected with Triton X-100, Polysorbate 80 (Tween 80), TnBP and/or caprylic acid or caprylate, preferably at final concentrations of  $\geq 0.1\%$  (w/w) Triton and Tween 80,  $\geq 0.03\%$  (w/w) TnBP,  $\geq 0.1$  mM caprylic acid or caprylate, with an incubation time of  $\geq 0.1$  hours, preferably  $\geq 1$  hour, at  $\geq 4$  °C, especially at  $\geq 15$  °C.

5. The process according to any of claims 1 to 4, wherein the salt concentration of the solution is brought to  $\geq 0.5$  M in step (c) and particles formed thereby are preferably removed by filtration.
6. The process according to any of claims 1 to 5, wherein chromatography on hydrophobic chromatographic materials is performed.
7. The process according to any of claims 1 to 6, wherein a treatment of the A1AT-containing fraction with a material which contains heparin in an immobilized form (heparin gel) is performed.
8. The process according to any of claims 5 to 7, wherein a further virus inactivation step is performed afterwards, preferably pasteurization in the presence of  $\geq 0.5$  M sodium citrate, amino acids, sugars or mixtures thereof.
9. The process according to any of claims 1 to 8, wherein the ion strength of the solution is preferably reduced by ultra-/diafiltration.
10. The process according to any of claims 1 to 9, wherein a separation of virus particles is performed, preferably by nanofiltration, preferably with filters having pore sizes of 15-20 nm.
11. The process according to any of claims 1 to 10, wherein the A1AT fraction obtained is stored as a liquid, frozen or freeze-dried preparation.
12. A1AT having a purity of  $> 90\%$ , an activity of  $\geq 0.8$  PEU/mg in its active form, an IgA content of  $\leq 1$  mg/ml, a residual detergent content of  $< 50$  ppm, especially  $< 10$  ppm, and a monomer content of  $> 90\%$ , based on the total amount of A1AT.
13. The A1AT according to claim 12, obtainable by a process comprising the following steps:

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- reconstitution of plasma fraction IV1 (Cohn);
  - anion-exchange chromatography on DEAE-Sepharose® Fast Flow;
  - optionally chromatography on a solid phase which comprises heparin in an immobilized form (heparin affinity chromatography);
  - optionally hydrophobic interaction chromatography (HIC);
  - virus inactivation with  $\geq 0.1\%$  (w/w) Triton/ $\geq 0.03\%$  (w/w) TnBP with an incubation time of  $\geq 1$  hour at  $\geq 15$  °C;
  - addition of salt to increase the ion strength of the solution; and
  - removal by filtration of particles formed thereby.
14. The A1AT according to claim 13, wherein a further virus inactivation step is performed afterwards, preferably pasteurization in the presence of  $\geq 0.5$  M sodium citrate, amino acids, sugars or mixtures thereof.
15. The A1AT according to claim 13, wherein the ion strength of the solution is preferably reduced by ultra-/diafiltration.
16. The A1AT according to claim 13, wherein a virus and/or prion depletion or inactivation step is comprised, preferably a separation of virus particles by nanofiltration, preferably with filters having pore sizes of 15-20 nm.
17. The A1AT according to claim 13, wherein the A1AT fraction obtained is stored as a liquid, frozen or freeze-dried preparation.
18. A medicament containing an A1AT according to any of claims 12 to 17 as a sole active ingredient or in combination with anti-inflammatory agents, preferably steroids, NSAIDs.

19. Use of the A1AT according to any of claims 12 to 17 for preparing a medicament for the treatment of A1AT deficiency, degenerative phenomena of the lung, such as lung fibrosis and emphysema.